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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/829,019	Applicant(s) GANNOE ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-19, 26, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/17/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 6/15/09.
2. The information disclosure statement(s) (IDS) submitted on 8/17/09 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-12, 17-19, 26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,542,949 to Yoon.

Yoon discloses a device comprising: an elongate main body 42 having a proximal end, a distal end, and a length therebetween; a first jaw member 46 and a second jaw member 48 each pivotally connected to the distal end of the main body, wherein the first and the second jaw members are adapted to move from a first configuration to a second expanded configuration in which the jaw members are translationally positioned into apposition with each other (via cams 120 and 122; col. 6, ll. 17), and wherein the first and the second jaw members each define an opening 86, 88 capable of acquiring a portion of a tissue within the opening, wherein the openings are in fluid communication with lumens defined in the main body (see Fig. 3); wherein

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the main body defines additional lumens (one for supplying staples 40 and one for the jaw members); wherein the device comprises a pull/push rod 89 for articulating the jaw members; wherein the device has a handle with ports and lever (Fig. 1); wherein the first and second jaw members are connected to the main body via crescent shaped hinges (Fig. 5; where jaw members 46 and 48 connect to inner cylinder 89) that are oriented 180 deg. from each other (flipped over); wherein the openings are at 180 degrees apart (see Fig. 3; the jaw members are mirror images and are oriented 180 deg. apart); wherein each of the openings extend into the jaw member along the longitudinal axis of the jaw member (including 0-5 cm. to 1 inch); wherein the device comprises a fastening assembly comprising staples 40; which assists in tissue healing, wherein the openings are a fenestration (opening in a surface).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon, as applied to the rejections above., and in further view of US 5,810,846 to Virnich et al.

Yoon discloses all the limitations of the claims except for the device having guide rod/wire. However, the use of a guide rod/wire in a stapler device is well known in the art, as shown in Fig. 3a of Virnich, element 104. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yoon to include a guide rod/wire as it will allow a practitioner to guide the device into the surgical site.

9. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon, as applied to the rejections above.

Yoon discloses all the limitations of the claims except for the opening comprising a plurality of fenestrations. However, Marucci discloses that it known in the tissue grasping art to have a plurality of openings/perforations/fenestrations along the surface

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of the jaw member to be utilized as a additional means of grasping tissue via suction (page 10, lines 25-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yoon to have the plurality of openings along the jaw members because it would provide an additional means of grasping the tissue.

Response to Arguments

10. Applicant's arguments regarding US 5,954,731 to Yoon have been fully considered and are not found persuasive.

11. First, the applicant argued that Yoon fails to teach first and second jaw members that are adapted to move from a first (unexpanded) position to a second expanded position in which the jaw members are translationally positioned into apposition with each other. This is not found persuasive as the jaw members 46 and 48 of Yoon includes outer cams 120 and 122, which causes the jaw members to close (or be in an unexpanded position) when biased against the outer tube 90. The jaw members 46 and 48 also has a second expanded position, as seen in Fig. 2. Note that the term "apposition" is defined as "placing side by side or next to each other". The phrase "next to each other" is a relative term and does not limit the claim to mean that the two structures (jaw members) are in direct contact with each other.

12. Second, the applicant argued that the openings 86, 88 of Yoon are not capable of acquiring tissue therewithin. However, as acknowledged by the applicant in the remarks, the openings 86 and 88 are indeed connected to a vacuum source. Thus, when the outer surface of the jaw members are resting against a tissue, the openings

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are fully capable of suctioning said tissue (a small portion of that tissue) within the openings.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773